

THURSDAY, JUNE 21, 2007

**Statement by Congressman Pete Stark
Supporting the Fair Balance Prescription Drug Advertisement Act**

Madam Speaker, I rise today to introduce the Fair Balance Prescription Drug Advertisement Act. This bill would place long overdue restrictions on direct-to-consumer, DTC, prescription drug advertisements. All too often, these poorly regulated ads provide incomplete and misleading information about new pills, pushing unnecessary prescriptions and promoting drugs before doctors and scientists have time to learn enough about their dangers.

Consumers, at whom these ads are targeted, don't realize that FDA approves drugs without confirming that they are safe for every treatment circumstance. As a result, many new drugs are widely marketed before the FDA discovers serious side effects and takes corrective action. Examples include drugs for conditions as common as arthritis and high blood sugar.

As scientists have discovered, "DTCA (direct to consumer advertising) is a successful method of generating prescriptions." Since ad restrictions were gutted in the U.S., drug advertising has grown at a startling rate, to a whopping \$4.2 billion in 2005. No surprise, drug costs have grown dramatically as well, from 78 billion in 1997 to more than 2 trillion in 2005. Pharmaceutical companies spend billions of dollars trying to convince consumers their drugs will fix everything from bad sex lives to bad moods. These ads lead consumers to demand drugs that may not be medically necessary or appropriate for their condition.

In many instances, DTC ads promote drugs that are later found to harm patients. In 2003, for example, Johnson & Johnson ran ads where Procrit seemed to rescue a cancer victim from disabling lethargy. Then new research came out showing cancer patients did no better on Procrit. In fact, some cancer patients actually did worse.

The FDA has now given Procrit a black box warning cautioning against the use of this drug in certain circumstances. The agency has also warned Johnson & Johnson and Amgen that there is no evidence to support marketing efforts suggesting the drug reduces fatigue for

patients in chemotherapy.

By increasing demand for pricey new drugs when cheaper ones will do, DTC advertising also drives up the costs of prescriptions. Sadly when patients find they can't afford these expensive drugs, they skip doses or don't even start the treatment. Unbalanced ads for expensive pills therefore contribute to both higher costs and to poor control of chronic disease.

The Fair Balance Prescription Drug Advertisement Act will empower the FDA to determine whether pharmaceutical companies present information about their products in a fair manner, balancing risks and benefits. Any advertisements found to violate this standard would be denied currently allowed business expense tax deductions for advertising costs.

Based on recommendations from the Institute of Medicine, the bill goes one step further and eliminates the business exemption for all new medications for the first 2 years that they are in the marketplace. This provision would provide doctors and scientists the opportunity to learn more about drugs' effects on a general population before consumers are bombarded with marketing pitches. Had this regulation been in effect when Procrit was introduced, many people would be better off today.

There are freedom of speech concerns with directly prohibiting advertising, accurate or not. This legislation therefore takes a different approach, hitting drug companies where it hurts them most, their bottom lines. While companies could continue running misleading ads, they would have to pay significantly more to do so. This will discourage drug companies from engaging in dishonest marketing practices.

The Fair Balance Prescription Drug Advertisement Act sets forth new guidelines that will help the pharmaceutical industry appropriately educate the public, enabling consumers to make informed decisions based on a fair and balanced presentation of risks and benefits. Today's DTC ads simply don't meet that standard. Given rapidly rising health care and prescription drug costs, we need to take every step we can to make prescription drugs safer and more affordable. We have to make sure advertisements aid consumers in making informed decisions, rather than simply increasing demand for the newest drugs.

Since the pharmaceutical industry already argues that their ads inform consumers, they

should have nothing to fear from this bill. We should pass this bill immediately and take a concrete step to improve the safety and efficacy of prescription drugs for America's consumers. I urge all my colleagues to join me in support of the Fair Balance Prescription Drug Advertisement Act.